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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,602	12/31/2003	Daryll A. Emery	293.00010102	8548

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MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER	
LEITH, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,602	EMERY ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-84* is/are pending in the application.

4a) Of the above claim(s) *45-66 and 70-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-44,67-69,83 and 84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 34-84 are pending in the application.

Claims 45-66 and 70-82 were withdrawn from consideration on the merits in the previous Office Action as they are directed toward a non-elected invention.

Claims 83 and 84 are new.

Claims 34-44, 67-69 and 83 and 84 were examined on their merits.

Applicant's arguments are essentially moot in light of the new rejections which follow. However, relevant arguments will be answered *infra*.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-44 and 67-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. US 6,682,754. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Instant claims are made obvious by claims 1-14 of '754.

Claims 1-14 of '754 teach a method for inducing immunity in a bird via implantation in ovo of a biocompatible implant providing for delayed and sustained release of an immunogen, wherein the implant is injected during the fourth quarter of

incubation, during 15-28 days of incubation and day 17-19 of incubation of an egg and wherein the implant provides for sustained release of the immunogen for about 1-90 days or 1-60 days or 1-35 days post-hatching.

The claims of 1-14 do not specifically teach wherein the immunogen is a siderophore receptor such as enterochelin. However, the patent teaches that a preferred immunogen is enterochelin (see col. 10 line 45). Therefore, enterochelin is encompassed by the term 'immunogen'.

This rejection remains pending because Applicant has neither convincingly traversed this rejection, nor has applicant furnished any terminal disclaimer in order to overcome this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-44, 83 and 84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 34 and 84 newly recite the phrase "...wherein the implant provides for sustained release of the immunogen **at least until** the bird is capable of mounting an immune response". This phrase is not found in the Disclosure as originally filed, and is deemed to differ in scope from that which was originally disclosed. Applicant is asked to either point out in the Specification where this information can be found, or delete/amend the claims in order to overcome this rejection.

Because claims 35-44 and 83 depend directly or indirectly from claim 34, these claims necessarily possess all of the limitations of claim 35 and thus also contain new matter and are properly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34, 37 and 39-43 remain rejected and claims 67-69, 83 and 84 are newly under 35 U.S.C. 103(a) as being unpatentable over Emery et al. (US 5,830,479) in view of Phelps et al. (US 5, 339,766) in view of Genovese et al. (1998).

The teachings of Emery et al. and Phelps et al. were keenly discussed in the previous Office Action. It is further noted that Emery et al. specifically taught the advantageous incorporation of adjuvants such as porins from many sources (see for example, col. 7, line 50- col. 8, line 10).

Neither reference specifically taught sustained release of the immunogen at least until the bird is capable of mounting an immune response to the immunogen

Applicant argues that Emery et al. do not provide for "sustained release of the immunogen at least until the bird is capable of mounting an immune response to the immunogen". "Though Applicants note that *injection* of the immunogen, as recited by the claims, may occur well before a time when maternal antibodies to the immunogen are sufficiently reduced" (p. 11, Arguments).

Genovese et al. (1998) discussed the problematic nature of poultry vaccinations :

> "Vaccinations currently used on newly hatched chicks and poults do provide some levels of protection from pathogens which poultry encounter early on in life as well as adult life. However, upon vaccination, the typical humoral/cell-mediated immune response requires 7 to 10 days to reach protective levels while poultry have been show to be most susceptible to bacterial species such as Salmonella during the first 4 days of life...In addition, maternal antibodies may cause interference with the vaccine and the desired immune response to this vaccine. With this in mind, it would be advantageous to administer an agent which could potentiate an immediate immune response for protection during the 4 to 7 days when the birds are most susceptible to these bacterial invaders and vaccination responses have not yet taken full effect" (see page 5).

One of ordinary skill in the art would have been motivated to administer a sustained-release formulation *in ovo*, to a bird (i.e., poultry such as chicken) wherein the formulation comprised a siderophore receptor such as enterochelin, and wherein the sustained-release formulation was sustained until the hatching of the bird (i.e., 1-60 or 1-90 days post-hatching) in order to increase the bird's immune system to foreign

disease causing bacteria. It was clear from the prior art that siderophore receptors from gram-negative bacteria were known to vaccinate birds, and suggested for use *in-ovo* by Emery et al. Further disclosed by Emery et al. as well as Phelps et al. were suitable mediums and sustained release biocompatible matrices for *in-ovo* injection of vaccines. The ordinary artisan would have recognized that the most crucial time of vaccination delivery to a young bird is within the first few days of life, as evidenced by Genovese et al., and hence would have had a reasonable expectation that formulating a biocompatible matrix which sustained the release of enterochelin would have been beneficial to the health of the bird, in that the bird, upon injection with the enterochelin, would create antibodies to the gram-negative bacteria thereby increasing the bird's immune system to that bacteria.

It is further noted that although the language 'at least until' was found to be New Matter, it was nonetheless examined with regard to the prior art. It is deemed that 'at least until the bird is capable of mounting an immune response to the immunogen' is broad enough to be directed toward any time after injection of the immunogen because it is deemed that the bird will elicit at least some immune response to the immunogen *in-ovo.*

It is noted that the term 'delayed' not being specifically defined within the Specification is given its broadest interpretation within reason. It is deemed that 'delayed' with regard to claim 34, can mean delayed release of the carrier, as claim 67

does not specifically state 'delayed release of the immunogen'. Further, 'delayed' can mean 'not immediate'. It is clear from Emery et al. that the immunogens are administered with carriers and adjuvants. It is deemed that release of the immunogen would be 'delayed' when administered with carriers and adjuvants compared to a vaccine which was administered without carriers and adjuvants.

Claims 34-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emery et al. (US 5,830,479) in view of Phelps et al. (US 5, 339,766) and further in view of Evans et al. (US 6,500,438 B2) in view of Genovese et al. (1998).

The teachings of Emery et al., Phelps et al. and Genovese et al. (1998) were discussed *supra.* None of the references taught the specific injection protocols as recited in claims 35, 36, 38 and 44.

Evans et al. (US 6,500,438 B2) taught a method for *in ovo* vaccination of chickens with *E. sporozoites* via injection, wherein the injection was preferentially performed in the final quarter of incubation or specifically at day 18 of incubation, however would have been effective during any time of incubation (col. 2, lines 1-6, col. 3 lines 25-27 and Example 1).

Although the prior art did not teach the specific injection times, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Although the prior art do not teach all the various permutations of injection times/release times, it would be conventional and within the skill of the art to identify the optional administration times as well as release times because (1) it was well known in the art that newborn mammals have weakened immune systems, (2) *in-ovo* administration of enterochelin to challenge the immune systems of incubating poultry embryos was clearly suggested by Emery et al. and arginine and (3) sustained delivery systems for vaccines; i.e., biocompatible polymer coatings/matrices were known and suggested for in-ovo delivery of vaccines.

Applicant argues that Evens et al. is directed toward administration of an immunogen which is different than that which is claimed and hence does not support this rejection. However, Evans et al. support the rejection because Evans et al. teach that it was known to inject poultry at the claimed times in order to illicit an immune response regardless of what type of immunogen they were administering.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary and absent any unexpected results.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

March 20,2006